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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/776,044

02/26/1997

MARGARET BYWATER

1614-178P

1463

2292

7590

11/14/2005

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/776,044	Applicant(s) BYWATER ET AL.	
	Examiner MISOOK YU, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,10 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,10 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

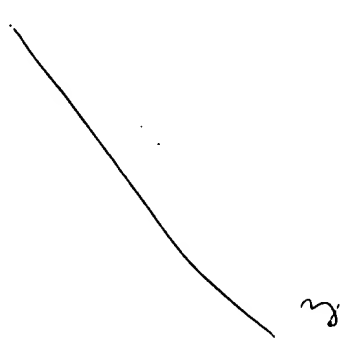
Claims 1-7, 9, 10, and 16-20 are pending and under consideration. This Office action contains new grounds of rejection. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103, Withdrawn

The rejection of claims 1-7, 9, and 16-20 under 35 U.S.C. 103(a) as being unpatentable over Allred et al., J Natl Cancer Inst. 1993 Feb 3;85(3):200-6 in view of US 5527676 A of record (the effective filing date of 1989) is withdrawn because applicant argument is persuasive.

The rejection of claims 1, 3, and 10 under 35 U.S.C. 103(a) as being unpatentable over Allred et al., J Natl Cancer Inst. 1993 Feb 3;85(3):200-6 in view of US 5527676 A of record (the effective filing date of 1989), further in view of Hedrum et al., of record, Biotechniques. 1994 Jul;17(1):118-9, 122-4, 126-9 is withdrawn because applicant argument is persuasive.

The rejection of Claims 1, 2, and 19 under 35 U.S.C. 103(a) as being unpatentable over Allred et al., J Natl Cancer Inst. 1993 Feb 3;85(3):200-6 in view of US 5527676 A of record (the effective filing date of 1989), further in view of Hollstein et al., of record (1991, Science, vol. 253, pages 49-53) is withdrawn.



The Following Is New Ground of Rejection

Claim Rejections - 35 USC § 112

Claims 1-7, 9, 10, and 16-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of the claims says that the claimed invention is a method of prognostication of the development of neoplasia and providing guidance on treatment. It is not clear what is meant by "prognostication of the development of neoplasm" in the preamble. The sample for p53 nucleic acid analysis in the active steps of the claims is from a human neoplastic tissue or body fluid. Thus, one in the art already has the information that the subject has developed neoplasia before doing the analysis in the active steps of the claims. It is not clear how the purpose stated in the preamble of the claims is related to the active steps of the claims.

Claims 1-7, 9, 10, and 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for p53 mutational analysis and node status analysis, does not reasonably provide enablement for providing guidance for the treatment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered for enablement analysis have been stated during the prosecution history, namely the Office action mailed on 6/10/98 (note pages 5-7).

At least one part of the claimed invention in claims 1-7, 9, 10, and 16-20 is drawn to method of providing treatment guidance after the p53 mutation and nodal status determinations.

Andersssohn et al., Ann Oncol. 2005 May;16(5):743-8 at Table 1, page 744 teach that one of skill in the art is able to determine p53 mutations, and also able to determine lymph node metastases, and how to use three different adjuvant therapies of CMF, TAM, CMF-TAM for breast cancer patients. Applicant argued that the claimed invention covers four different subgroups of the patients in the reply filed on 11/10/98, in response to the enablement rejection made at pages 5-7 of the Office action mailed on 6/10/98.

The specification does not teach what kinds of treatment is good for each of those patients in the different subgroups classified based on nodal status and the p53 mutational status. However, Falette et al., Cancer Res. 1998 Apr 1;58(7):1451-5, which was published almost 3 years after the effective filing date of the instant application teach at the last two sentences of the abstract "Our results suggest that P53 gene mutations could be an important factor to identify node-negative patients who have a poor prognosis in the absence of adjuvant therapy. Prospective studies should be designed to determine which therapy should be performed in this subgroup of patients." This suggests that one of skill in cancer treatment art does not know what kind of treatment is appropriate for those node negative, but p53 mutation positive breast cancer patients, let alone many other different types of cancer, even three years after the filing date of the instant application.

Considering the state of art, limited guidance for what kind of treatment is appropriate for each subgroups of patient, and broad scope of the claims including any cancer, undue experimentation is required to practice the full scope of the invention.

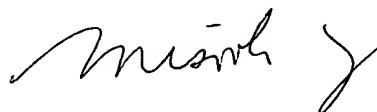
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

A handwritten signature in cursive script, appearing to read 'Misook Yu', is written below the printed name.